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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,694	01/24/2002	Stephane Gobron	CL/V-31975A	1035
1095	7590	02/16/2007		
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			EXAMINER MAYES, MELVIN C	
			ART UNIT	PAPER NUMBER
			1734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/16/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/056,694

Applicant(s)

GOBRON ET AL.

Examiner

Melvin Curtis Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-10,12-20,22-34 and 48-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3-9 and 48-55 is/are allowed.
- 6) ☒ Claim(s) 10,12-20 and 22-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

(1)

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2006 has been entered.

### ***Claim Rejections - 35 USC § 112***

(2)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(3)

Claims 10, 12-20 and 22-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 claims that the cavity has a variable volume between a first volume and a second volume and claims that the sample volume is greater than the first volume. It is not clear what is considered "first volume." Is this the volume of the cavity when the mold parts are moved together to form the lens (i.e. the first volume is the volume of the formed lens) or is the first volume the minimum volume that the cavity can achieve if there was no sample in the

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cavity (the present specification describes a minimum volume and maximum volume of the mold). For purposes of examination, "first volume" is interpreted to refer to the final volume of the cavity when the mold parts are moved together to form a lens.

***Claim Rejections - 35 USC § 103***

(4)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(5)

Claims 10, 12-20, 22, 24, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754.

EP 0 131 227 (EP '227) discloses a method of making a contact lens comprising: extruding a film (ribbon) of thermoplastic processable material (thus at a temperature between 50°C below the glass transition temperature and 50°C above the degradation temperature); punching a blank from the film; placing the blank on a concave molding die (first mold part) and closing a convex molding die (second molding part) on the blank such that the blank is between convex and concave molding dies (first and second mold parts); and molding the blank at a temperature higher than the glass transition point of the thermoplastic material by 20-80°C but lower than the melt flow temperature thereof (thus between 120°C below glass transition temperature and the degradation temperature) at a pressure of 10-100 kg/cm<sup>2</sup> for 5-120 minutes to form the contact lens while prevent the escape of thermoplastic material during the molding. EP '227 discloses that the film can have a thickness of 0.1-1 mm (thus between 50 microns and 5

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mm), discloses providing the blank to be placed molded with a weight within  $\pm 0.5$  mg of the desired weight of the molded element, discloses hydrating the contact lens and discloses that the thermoplastic material can be selected from: cellulose ester, homopolymer or copolymer of methacrylate ester, acrylate ester, styrene, acrylonitrile and vinyl chloride; polycarbonate, polyamide or a polymer blend of these (which includes polymers which are hydrophilic, form a hydrogel when hydrated or contain latent crosslinking groups) (see also corresponding document JP 60-49906). EP '227 does not specifically disclose providing the molding dies (mold parts) with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes.

Yang et al. 6,042,754 teaches that in molding ophthalmic lenses using upper and lower dies, the die set can be provided such that only air is vented out and all of the material is kept inside of the die set (col. 11, lines 49-52).

It would have been obvious to one of ordinary skill in the art to have modified the method of EP '277 for making a contact lens by providing the two dies with clearance such that gas escapes from the mold cavity but none of the thermoplastic material (polymer) escapes, as taught by Yang et al. for making an ophthalmic lens using a pair of dies.

Punching the blank from the film by a punch and die wherein a molding die is placed below the punch and die such that the punched blank is clamped between the punch and die and drops through the die into the molding die would have been obvious to one of ordinary skill in the art to allow punching and molding of the thin and fragile blank without handling between punching and molding steps.

By providing a punched blank having a weight within  $\pm 0.5$  mg of the desired weight of the molded lens, the blank (sample) obviously has a volume which overlaps the claimed range of volume between 0.01% and 10% greater than the first volume of the mold cavity. By providing the punched blank with a weight of 0.5 mg more than the desired weight of the molded lens, the blank obviously has a volume at least 0.01% greater than the volume of lens to be formed and thus a volume at least 0.01% greater than the volume of the cavity when the blank is molded to form the lens (first volume).

Using an extruder having a closed-loop pressure feedback control system coupled to the pump, as claimed in Claim 16, would have been obvious to one of ordinary skill in the art as a suitable extruder that can be used to extrude the polymer.

(6)

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 as applied to claim 22, and further in view of either Yang et al. 6,015,512 or Lefebvre 5,458,820.

Yang et al. teach that mold dies for making thermoplastic optical articles are cleaned in distilled water and dried before use for molding (col. 9, lines 5-6).

Lefebvre teaches that before molding a thermoplastic ophthalmic lens, the molding surfaces are preferably wiped with acetone to degrease them and render them chemically clean (col. 7, lines 1-3).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by cleaning the molding dies after molding, as taught by Yang et al. or Lefebvre, to process the dies for reuse for molding contact lenses.

(7)

Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 as applied to claim 10, and further in view of WO 00/53401 (WO '401) Abstract.

EP '277 discloses molding the contact lens blank for 5-120 minutes to form the contact lens (thus encompassing less than 500 seconds as claimed in Claim 30). EP also discloses that the film can have a thickness of 0.1-1 mm (thus between 0.05 mm and 1.0 mm as claimed in Claim 26).

WO '401 Abstract teaches that in making a contact lens having no air inclusions and clean and thin edge, a three-part mold is used which defines a molding cavity and a drainage and retention volume to accept excess molding compound and pull away the excess during disassembly.

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by providing the molding dies with a third part so as to form a drainage and retention volume, as taught by WO '401 Abstract, to form a contact lens having no air inclusions and a clean and thin edge. By providing the molding dies with a third part such that excess blank is accepted and pulled away, the mold cavity is provided with a flange mold cavity into which a flange is formed and removed from the contact lens, as claimed.

(8)

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 131 277 in view of Yang et al. 6,042,754 as applied to claim 10, and further in view of Yamanaka et al. 6,099,765.

Yamanaka et al. teach that funnel-shaped holding pad formed of silicon rubber and connected to a vacuum source for holding optical material to the holding pad is used to hold optical material when moving it into and away from the mold apparatus (col. 4, lines 17-25).

It would have been obvious to one of ordinary skill in the art to have modified the method of the references as combined by using a silicon rubber pad and vacuum to separate the lens from the molding dies, as taught by Yamanaka et al., as known for use to hold optical material when moving it away from the mold apparatus.

***Allowable Subject Matter***

(9)

Claims 1, 3-9 and 48-55 are allowed.

***Response to Arguments***

(10)

Applicant's arguments filed November 20, 2006 have been fully considered but they are not persuasive.

EP 0 131 227 is not directed to conventional injection molding in which the cavity is defined by the mold itself but clearly discloses using first and second mold dies between a blank is placed and bring the mold parts together with pressure to form a lens from the blank.




***Conclusion***

(11)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melvin Curtis Mayes whose telephone number is 571-272-1234. The examiner can normally be reached on Mon-Fri 7:30 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on 571-272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Melvin Curtis Mayes  
Primary Examiner  
Art Unit 1734

MCM  
February 12, 2007